UNITED STATES DISTRICT COURT
FOR THE
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA;
STATE OF CALIFORNIA;
STATE OF DELAWARE;
STATE OF FLORIDA;
STATE OF GEORGIA;
STATE OF HAWAII;
STATE OF ILLINOIS;
STATE OF INDIANA;
STATE OF LOUISIANA;
COMMONWEALTH OF MASSACHUSETTS;
STATE OF MICHIGAN;
STATE OF MONTANA;
STATE OF NEVADA;
STATE OF NEW HAMPSHIRE;
STATE OF NEW JERSEY;
STATE OF NEW MEXICO;
STATE OF NEW YORK;
STATE OF NORTH CAROLINA;
STATE OF OKLAHOMA;
STATE OF RHODE ISLAND;
STATE OF TENNESSEE;
STATE OF TEXAS;
COMMONWEALTH OF VIRGINIA;
STATE OF WISCONSIN;
DISTRICT OF COLUMBIA;
CITY OF CHICAGO, ILLINOIS; and
CITY OF NEW YORK, NEW YORK,

Ex rel. FOX RX INC.,

PLAINTIFFS/RELATOR,

v.

Dr. REDDY'S INC.; OMNICARE, INC.; and
NEIGHBORCARE, INC.,

DEFENDANTS.

FILED UNDER SEAL
AND *IN CAMERA*

Civ. No.

COMPLAINT

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On behalf of the United States of America, and itself, and on behalf of the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, the Commonwealth of Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, the Commonwealth of Virginia, Wisconsin, the District of Columbia and the City of Chicago, Illinois and the City of New York, New York (collectively "the States"), Relator Fox Rx, Inc. ("Relator" or "Fox Rx") files this *qui tam* Complaint against Defendants Dr. Reddy's, Inc. ("Dr. Reddy's") Omnicare, Inc. ("Omnicare") and Neighborcare, Inc. ("Neighborcare") (collectively "Defendants"), and allege as follows:

I. INTRODUCTION

1. This Complaint arises from Defendants' unlawful kickbacks associated with the generic prescription drug simvastatin.

2. Under this kickback scheme, Dr. Reddy's paid Omnicare and its subsidiary Neighborcare (collectively "Omnicare") incentive kickbacks in the form of rebates to illegally induce Omnicare to sell simvastatin to its clients, long term care skilled nursing facilities, for their patients with high cholesterol.

3. As part of the scheme, Omnicare and Dr. Reddy's knowingly caused false claims to Medicare Parts A and D and Medicaid and other federal health care programs that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in reimbursements that should not have been paid.

4. Dr. Reddy's manufactures simvastatin in India and sells it to Omnicare, in many instances at a higher price than domestically manufactured generic simvastatin. Simvastatin manufactured by Dr. Reddy's has been subject to recall because several batches have been tainted with pesticides.

5. The Federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b) the ("AKS"), expressly prohibits any individual or entity from offering, paying, soliciting or receiving any "remuneration," which "include[s] any kickback, bribe, or rebate," to "any person to induce such person" to purchase or recommend a drug or service that is covered by Medicare or Medicaid. *Id.* In that regard, to qualify for most Medicare and Medicaid payments, pharmacies must certify that they are complying with the AKS. Further, as early as 1994, the Government gave notice to pharmaceutical companies like Dr. Reddy's that they could be in violation of the AKS by offering financial benefits to a pharmacy in exchange for promoting one prescription drug over another prescription drug. *See* 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

6. Although Dr. Reddy's knew that the AKS prohibited it from giving, and Omnicare from receiving kickbacks to promote simvastatin, they disregarded that prohibition, choosing instead to put sales growth and profits before the duty to comply with federal law. Specifically, from at least 2007 until the present, Dr. Reddy's offered kickbacks (by the total number of units of simvastatin sold) to Omnicare that influenced whether simvastatin or a competitor's cheaper generic simvastatin was prescribed to patients in long-term skilled nursing homes, and disguised these kickbacks as "rebates." In addition to reimbursement from Medicare Part A, Omnicare also sought reimbursement for simvastatin under the Medicare Part D program. In exchange for the kickbacks from Dr. Reddy's, Omnicare agreed to disregard its professional independence, and use its influence to switch patients to simvastatin purchased from Dr. Reddy's instead of competitor's drugs with higher quality assurance measures and a safer product history.

7. The rebates Dr. Reddy's paid to Omnicare for simvastatin were entirely retained by Omnicare and not submitted or passed on to government-sponsored healthcare programs. No

other foreign or domestic generic simvastatin manufacturer paid such incentive rebate to Omnicare.

8. As a result, Dr. Reddy's captured over 90% of the Omnicare simvastatin market, even though Dr. Reddy's charged higher prices and maintained lower quality control than domestic manufacturers of generic simvastatin. Dr. Reddy's capture of the Omnicare market share for generic simvastatin was a direct result of the illegal rebates/kickbacks paid by Dr. Reddy's to Omnicare.

A. Federal False Claims Act

9. This action seeks to recover treble damages and civil penalties on behalf of the United States of America arising from the conduct of Dr. Reddy's and Omnicare that: (a) made, used, or presented, or caused to be made, used or presented, certain false or fraudulent statements, records and/or claims for payment or approval to the United States of America; and/or (b) made, used or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the United States, all in violation of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (the "FCA").

10. The false or fraudulent claims and statements at issue involve payments for prescription drugs made by: (a) Federally-funded health assistance programs, including Medicaid and Medicare; (b) Federally-funded health insurance programs, including the Federal Employees Health Benefits Program ("FEHBP"), TRICARE/CHAMPUS, the United States Postal Service; and (c) other Federal Government purchases, including payments made by the Department of Defense, the Department of Veterans Affairs ("VA"), and other Federal programs such as the Indian Health Service.

B. State False Claims Acts

11. This action seeks to recover damages and civil penalties on behalf of the named States arising from the conduct of Dr. Reddy's and Omnicare which:

> (a) made, used, or presented, or caused to be made, used or presented, certain false or fraudulent statements, records and/or claims for payment or approval to the States; and/or (b) made, used or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the States,

all in violation of each State's respective False Claims Act or similar statute. The false or fraudulent claims and statements at issue involve payments made by State-funded health assistance and insurance programs, including Medicaid, and payments made by other State-funded agencies or entities, such as hospitals.

12. The statutes of the States under which Relator brings these related actions are the:

a. California False Claims Act, Cal. Govt. Code §§ 12650, *et seq.*;

b. Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201, *et seq.*;

c. Florida False Claims Act, Fla. Stat. §§ 68.081, *et seq.*;

d. Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168, *et seq.*;

e. Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21, *et seq.*;

f. Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1, *et seq.*;

g. Indiana False Claims and Whistleblower Protection Act, In. Code §§ 5-11-5.5, *et seq.*;

h. Louisiana False Claims Act/Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. Ch. 3 §§ 437.1, *et seq.*;

i. Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §§ 5A, *et seq.*;

j. Michigan Medicaid False Claims Act, MCLS §§ 400.601, *et seq.*;

k. Montana False Claims Act, Mont. Code §§ 17-8-401, *et seq.*;

l. Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010, *et seq.*;

m. New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61, *et seq.*;

n. New Jersey False Claims Act, N. J. Stat. Ann. §§ 2A:32C-1, *et seq.*;

o. New Mexico Medicaid False Claims Act, N.M.S. §§ 27-14-1, *et seq.*;

p. New York False Claims Act, N.Y. Fin. Law §§ 187, *et seq.*;

q. North Carolina False Claims Act, N. C. Gen. Stat. Ann. §§ 1-605, *et seq.*;

r. Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. §§ 5053, *et seq.*;

s. Rhode Island False Claims Act, R. I. St. §§ 9-1.1-1, *et seq.*;

t. Tennessee Medicaid False Claims Act, Tenn. Code §§ 71-5-181, *et seq.*;

u. Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001, *et seq.;*

v. Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1, *et seq.*;

w. Wisconsin False Claims Act, Wis. Stat. Ann. §§ 20.931 (1), *et seq.*;

x. District of Columbia False Claims Act, D.C. Code §§ 2-308.03, *et seq.*;

y. Chicago False Claims Act, Municipal Code ch.1, §§ 22-010, *et seq.*; and

z. New York City False Claims Act, N.Y.C. Admin. Code, §§ 7-801, *et seq.*

II. JURISDICTION, VENUE AND STATUTORY REQUIREMENTS

13. Pursuant to 28 U.S.C. § 1331, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States, in particular, the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* In addition, the False Claims Act specifically confers jurisdiction upon the United States District Court. 31 U.S.C. § 3732(b).

14. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the False Claims Acts of the States and Cities on the grounds that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 31 U.S.C. § 3730. 31 U.S.C. § 3732(b).

15. This District Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because the False Claim Act authorizes nationwide service of process and the Defendants have sufficient minimum contacts with the United States of America.

16. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because acts complained of herein occurred within this judicial district. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (c), because Defendants transact business in this District and, in furtherance of their fraudulent kickback scheme, caused to be submitted or conspired to submit false claims in this District.

III. THE PARTIES

A. Relator Fox Rx Inc.

17. Relator Fox Rx brings this action for violations of the FCA on behalf of itself, the United States of America pursuant to 31 U.S.C. § 3730(b)(1), and on behalf of the States pursuant to their respective statutes. Fox Rx is a Delaware corporation, and is the parent Corporation of Fox Insurance Company, a Delaware corporation that was, from 2006 to 2010, engaged in the business of sponsoring Medicare Part D PDPs.

18. Plaintiff United States of America, acting through the Department of Health and Human Services ("HHS"), and its Centers for Medicare and Medicaid Services ("CMS") administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* (Medicare), and Grants to States for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* (Medicaid).

19. Defendant Omnicare, Inc., is a Delaware corporation headquartered in Cincinnati, Ohio. Omnicare is the nation's largest provider of pharmacy services to nursing homes and other long term care facilities ("LTCFs"). Through contracts with these facilities, it serves as a consulting pharmacist and dispenses drugs to approximately 1.4 million long-term care residents in 47 states (including New York), and the District of Columbia. Omnicare's market share includes 70% of the long term care pharmaceutical business in the United States. Approximately 44% of Omnicare's annual sales are paid by Medicare and approximately 9% of annual sales are paid by state Medicaid programs. As a dispensing pharmacy, Omnicare fills prescriptions for patients in LTCF, and for the first 100 days of the patient stay, Medicare Part A reimburses Omnicare for the cost of covered pharmaceuticals dispensed. Omnicare also fills prescriptions for beneficiaries of Medicare Part D. Beginning in 2006 and for all relevant periods to this complaint, Omnicare operated under a Corporate Integrity Agreement ("CIA") with CMS. That CIA specifically covered "Arrangements" with vendors such as Dr. Reddy's and specifically addressed measures to protect against kickback schemes as alleged in this complaint.

20. Neighborcare Inc., is a wholly owned subsidiary of Omnicare.

21. Defendant Dr. Reddy's Laboratories Ltd is a leading India-based pharmaceutical company headquartered at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500

034, India. Dr. Reddy's Laboratories Ltd United States operations are based at 200 Somerset Corporate Blvd #7, Bridgewater, New Jersey 08807. Dr. Reddy's Laboratories Inc. also maintains operations at 3600 Arco Corporate Dr. Suite 310, Charlotte, North Carolina 28273. Among other pharmaceutical products and services, Dr. Reddy's manufactures generics including simvastatin.

IV. GOVERNING LAWS, REGULATIONS AND CODES OF CONDUCT

A. The False Claims Act

22. The FCA, specifically 31 U.S.C. § 3729(a)(1) and (2), as amended, 31 U.S.C. § 3729(a)(1)(A), (B) & (G), imposes liability upon any person who: "knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;" or "knowingly makes, uses or causes to be made or used, a false record or statement to get false or fraudulent claims paid or approved;" or "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government." Any person found to have violated these provisions is liable for a civil penalty of up to $11,000 for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government.

23. The FCA imposes liability where the conduct is "in reckless disregard of the truth or falsity of the information" and "no proof of specific intent to defraud is required." 31 U.S.C. § 3729(B), as amended, 31 U.S.C. §3729(b)(1)(A) & (B). The FCA also broadly defines a "claim" as including "any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(c).

B. Government-Funded Health Assistance Programs' Laws and Rules Relating to Prescription Drugs

1. Medicare

24. Medicare is a Federal Government-funded medical assistance program, primarily benefiting the elderly, 42 U.S.C. §§ 1395, *et seq.* Medicare is administered by the Federal Centers for Medicare and Medicaid Services ("CMS"), which is a division of the United States Department of Health and Human Services ("HHS").

25. Part A of the Medicare Program provides benefits to participants to cover, among other things, health care provided in a long term care skilled nursing facility, including some prescription drugs, for the first 100 days of the beneficiary's stay in such facility.

26. Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries.

27. All persons enrolled in Medicare Part A are eligible to enroll in a prescription drug plan under Part D.

28. HHS, through its component agency, the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "sponsors") authorized to sell Part D insurance coverage. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts.

29. Medicare enters into provider agreements with providers and suppliers to establish their eligibility to participate in the program. During the relevant times, to be eligible for payment under Part A of the program, pharmacies must certify:

> I agree to abide by the Social Security Act and all applicable Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I

> understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

See, e.g. CMS Form 855S (04/06) at 26.

2. Medicaid

30. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's *per capita* income compared to the national average. *See* 42 U.S.C. § 1396d(b). Among the states, FMAP is at least 50 percent and is as high as 83 percent.

31. At the Federal level, Medicaid is administered by CMS. Medicaid is used by 49 states, each of which has a State Medicaid agency to administer the program.

32. The states are permitted to expend Medicaid Funds to provide medical assistance for eligible persons for inpatient and outpatient prescription drugs. 42 U.S.C. § 1396a(10)(A); 1396d(a)(12).

33. The Medicaid programs in all states reimburse pharmacies for prescription drugs. Under the Medicaid Drug Rebate Statute, 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1), and in exchange for Medicaid coverage for their drugs, drug manufacturers like Dr. Reddy's enter into national rebate agreements that require them to pay rebates to state Medicaid programs when their drugs are dispensed to Medicaid patients.

34. The States require certifications by pharmacists as a condition of providing Medicaid reimbursement for the prescriptions they write. In New York, for example, the Medicaid program requires a pharmacy to certify, *inter alia*, that it "agree[s] to abide by all

applicable Federal and State laws as well as the rules and regulations of other New York State agencies particular to the type of program covered by this enrollment application."

a. "Medically Necessary" and "Medically Accepted Indication" Preconditions for Reimbursement of Prescription Drugs

35. "Medically necessary" prescription drugs are those drugs that are needed for evaluating, diagnosing or treating an illness, injury, disease or its symptoms; meet the generally accepted standards of good medical practice; and are clinically appropriate, in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and are not primarily for the convenience of the patient or physician.

36. The Medicaid program reimburses only for "covered outpatient drugs" for which a rebate is paid by the drug's manufacturer. 42 U.S.C. § 1396b(i)(10). The term "covered outpatient drug" requires use for a "medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). A "medically accepted indication" includes only those indications approved by the FDA, and those "off-label" uses that are "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the statute. 42 U.S.C. § 1396r-8(k)(6); *see also* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (identifying the compendia to be consulted).

b. Medicaid "Best Price" Reporting and Rebate Requirements

37. Each State pays a portion of the Medicaid cost for goods and services provided to that State's Medicaid beneficiaries. Each State's portion varies depending upon various factors, but generally ranges from 40-60%, with the Federal Government paying the remaining portion.

38. In 1990, Congress enacted the Medicaid Rebate Program, 4 U.S.C. § 1396r-8, as part of the Omnibus Budget Reconciliation Act of 1990. The Medicaid Rebate Program (also known as the "Medicaid Rebate Act" and the "Medicaid Rebate Statute") is a cost-savings

measure Congress passed in response to increasing Medicaid expenditures for prescription drugs, requires drug companies to pay rebates to States on their Medicaid purchases.

39. Pursuant to 42 U.S.C. § 1396r-8(a)(1), drug manufacturers who want their drugs covered by Medicaid and Medicare must enter into a rebate agreement with the Secretary of HHS (the "Secretary") in order for Federal matching funds to be made available under these programs for that manufacturer's covered outpatient drugs.

40. Upon entering a Rebate Agreement with the Secretary, the manufacturer must pay a quarterly rebate directly to each participating State based on all of the manufacturer's drugs purchased by that State pursuant to its Medicaid plan during that quarter.

41. Pursuant to 42 U.S.C. § 1396r-8(c)(1)(2) for generic drugs, the basic rebate due on each unit paid for under the State plan is a flat 11% to 13% of the average manufacturers' price ("AMP") during the previous quarter rebate period, from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or non-excluded government entity (the "Best Price").

42. The Best Price must take into account "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates (other than rebates under this section)." 42 U.S.C. § 1396r-8(c)(1)(C)(ii). The Best Price also is determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, such as private labeling arrangements.

43. Drug manufacturers are required under the Medicaid Rebate Statute and the Rebate Agreement to calculate and report their AMPs and Best Prices to the Secretary on a quarterly basis. 42 U.S.C. § 1396r-8(3)(A)(i); Rebate Agreement at § II(e). States are required to report their total Medicaid drug utilization to each manufacturer and the Secretary 60 days

after the end of the rebate quarter. 42 U.S.C. § 13964-8(b)(2)(A). Using the manufacturer pricing data, CMS computes the unit rebate amount ("URA") to which the Medicaid utilization information may be applied by States when invoicing the manufacturer for the rebate payment due. Using the Medicaid drug utilization data, manufacturers calculate and pay the rebates that are due and owing to each State.

44. The Federal Government has great financial interest in the Best Price rebate program, since the statute provides that amounts received by the States from the manufacturers "shall be considered to be a reduction in the amount expended under the state plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title." 42 U.S.C. § 1396r-8(B)(1)(b). Hence, the entire system is based upon the manufacturer's honesty in conveying to CMS the correct Best Price and AMP information. Any overstatement of the Best Price, intentional or unintentional, will cause an underpayment in rebate amounts to each State. In turn, the underpayments to each State result in the Federal Government's cost-sharing payment to each State to be greater than it otherwise would have been.

45. In or about May 2003, as a result of pervasive Best Price fraud, the HHS Office of Inspector General ("OIG") promulgated compliance materials which observed that manufacturers have "a strong financial incentive to hide *de facto* concessions" (in particular, kickbacks, price discounts and rebates) that could affect Best Price calculations and trigger increased Medicaid rebates.

46. The OIG also instructed manufacturers to report Best Prices which "accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." In sum,

according to the OIG, "pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes."

3. The Anti-Kickback Statute

47. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) first enacted in 1972, reflects Congress' concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions do not evade its reach. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b. Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

48. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally funded medical services, including services provided under the Medicare, Medicaid and (as of January 1, 1997) TRICARE programs. 42 U.S.C. § 1320a-7b(b).

49. The Anti-Kickback Statute makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person—

(1) to refer an individual to a person for the furnishing of any item or service covered under a federal healthcare program; or

(2) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal healthcare program.

50. The term "any remuneration" encompasses any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. 42 U.S.C. § 1320a-7b(b)(1).

51. Parties who contract or subcontract with the Federal Government are subject to the provisions of the AKA. That law renders it impermissible for any person "to provide, attempt to provide, or offer to provide any kickback," and defines 'kickback' to mean "any money, fee, commission, credit, gift, gratuity, *thing of value*, or compensation of any kind which is provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor, or subcontractor employee *for the purpose of improperly obtaining or rewarding favorable treatment* in connection with a prime contract or in connection with a subcontract relating to a prime contract." 41 U.S.C. §§ 52 -53 (emphasis added).

52. Payments by a pharmaceutical company to pharmacies to induce them to recommend or purchase the company's drugs violate this statute to the extent that the drugs are reimbursed by a federal health care program.

53. Violations of the AKA are felonies punishable by fines and imprisonment, and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7(b)(2) and 42 U.S.C. § 1320a-7(b)(7).

54. As early as 1994, the Government made clear that the AKA prohibits drug manufacturers from offering financial incentives to pharmacies to induce increased use of prescription drugs covered by federal healthcare programs. 59 Fed. Reg. at 65,376 (Dec. 19, 1994).

55. Falsely certifying compliance with the AKA in connection with a claim submitted to a federally funded insurance program is actionable under the FCA. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, 6402(f), 124 Stat.

119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claims for purposes of [the FCA]."

56. Dr. Reddy's paid illegal kickbacks to Omnicare who purchased simvastatin and thus, caused Omnicare to falsely and expressly certify compliance with the AKA and to seek reimbursement from Medicare, Medicaid, and other Government programs for such false claims.

V. SIMVASTATIN

A. Nature and Usage of Simvastatin

57. Simvastatin is the generic equivalent to the brand-name statin Zocor. Simvastatin is designed to be used together with diet, weight-loss, and exercise to reduce the amount of fatty substances such as low-density lipoprotein (LDL) cholesterol ("bad cholesterol") and triglycerides in the blood and to increase the amount of high-density lipoprotein (HDL) cholesterol ("good cholesterol") in the blood. Simvastatin may also be used to decrease the amount of cholesterol and other fatty substances in the blood in children and teenagers 10 to 17 years of age who have familial heterozygous hypercholesterolemia (an inherited condition in which cholesterol cannot be removed from the body normally). Simvastatin is also used to decrease the risk of heart attacks, strokes, and death, and to decrease the need for surgery to improve blood flow in people who have medical conditions that put them at high risk of developing heart and blood vessel problems.

58. Simvastatin is in a class of medications called HMG-CoA reductase inhibitors ("statins"). It works by slowing the production of cholesterol in the body to decrease the amount of cholesterol that may build up on the walls of the arteries and block blood flow to the heart, brain, and other parts of the body.

59. Simvastatin is one of the most widely prescribed statins for the treatment of high cholesterol. Simvastatin is manufactured by several pharmaceutical companies in the United States and abroad and by Dr. Reddy's in India.

B. Omnicare and Dr. Reddy's Kickback Scheme

60. The Medicare and Medicaid programs include detailed statutory and regulatory provisions concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for full Federal participation, price controls on prescription drugs, and drug manufacturer rebate agreements.

61. At all relevant times, Dr. Reddy's and Omnicare were well aware that Medicare and Medicaid covered a substantial percentage of the simvastatin sales made by Dr. Reddy's to Omnicare to which it was paying illegal kickbacks in the form of rebates. Indeed, between 2007 and 2010 approximately 90% to as much as 100% of simvastatin sold by Omnicare was manufactured by and purchased from Dr. Reddy's.

62. In 2007 and earlier, every Medicare Part D plan received a Long Term Care Rebate Report from the plan's Pharmacy Benefit Manager ("PBM") for submission to CMS. CMS discontinued the Rebate Report requirement in 2008 onwards, finding such reports not useful.

63. The 2007 Rebate Report received by Fox Rx shows that Dr. Reddy's paid an "incentive" rebate to Omnicare for over 89% of its sales of simvastatin to Omnicare. Dr. Reddy's paid no such incentive rebate for any other pharmaceuticals sold to Omnicare. The volume of the other pharmaceuticals sold to Omnicare, for which no incentive rebates were paid was relatively small compared to the volume of simvastatin sold to Omnicare.

64. This "incentive" rebate paid by Dr. Reddy's was not passed on to Medicare or Medicaid, but instead was retained entirely by Omnicare. In effect, the incentive rebate was a

commission reward and incentive to Omnicare to purchase simvastatin from Dr. Reddy's. The illegal rebate was paid on each unit of simvastatin purchased from Dr. Reddy's. The Rebate Report also shows that Dr. Reddy's knew the magnitude of Medicare and Medicaid reimbursements for simvastatin sold to Omnicare. In addition, as a manufacturer, Dr. Reddy's received data from the Pharmacy Benefit Manager, after the drug was dispensed, showing whether the drug was for a Medicare or Medicaid beneficiary.

65. Many Omnicare patients are dual eligible Medicare Part D and Medicaid. Thus states are also affected by the Medicare Part D clawback from states' Medicaid Programs.

66. Records also show that Dr. Reddy's often charged Omnicare higher prices for simvastatin than domestic or other foreign generic simvastatin manufacturers charge for their simvastatin. Omnicare in turn sought reimbursement from Medicare and Medicaid for the higher costs of simvastatin charged by Dr. Reddy's. The pricing of Dr. Reddy's simvastatin that was dispensed by Omnicare was on average 60% higher than simvastatin dispensed by others, including domestic manufacturers.

67. Dr. Reddy's paid the incentive rebates to Omnicare consistently from at least 2007 through 2010.

68. By way of example, in 2009, Relator Fox Rx, as a Medicare Part D Sponsor, serviced approximately 4500 Omnicare patients, who had a total of 7000 claims for simvastatin for that year. Extrapolating to all Omnicare patients, Omnicare submitted approximately 815,000 claims for Dr. Reddy's simvastatin every year from 2006 (the year Medicare Part D benefits became available) to the present.

69. In addition, Omnicare charged Medicare Part D $5.75 as a dispensing fee for every simvastatin prescription dispensed—the highest dispensing fee charged in the pharmacy

industry for simvastatin. By way of example, CVS charged a dispensing fee of $1.80 for a 30-day supply of simvastatin.

70. As a direct result of their rebate/kickback scheme, Dr. Reddy's captured an overwhelming percent of Omnicare's simvastatin market share. In 2007, Dr. Reddy's supplied 89.69% of the simvastatin sold through Medicare Part D through the Medicare Part D plan sponsor Fox Insurance. In 2008, Dr. Reddy's supplied 100% of the simvastatin sold through Medicare Part D through the Medicare Part D plan sponsor Fox Insurance. In 2009, Dr. Reddy's supplied 97.2% of the simvastatin sold through Medicare Part D through the Medicare Part D plan sponsor Fox Insurance. In 2010, Dr. Reddy's supplied 99.76% of the simvastatin sold through Medicare Part D through the Medicare Part D plan sponsor Fox Insurance.

71. Dr. Reddy's also charged Omnicare some of the highest prices for generic simvastatin. For example in 2007, Novartis AG charged $0.001966, whereas Dr. Reddy's charged $0.002111 per unit of simvastatin 80mg (calculated as ingredient cost per unit to eliminate fluctuating factors such as sales tax and other variable costs). Also in 2007, Perrigo Company charged $0.001966, whereas Dr. Reddy's charged $0.002037 per unit of simvastatin 40mg.

72. In 2009, Blu Pharmaceutical's 80mg simvastatin and Perrigo Company's 20mg simvastatin were less expensive than Dr. Reddy's comparable dosages of simvastatin. In other years and with other dosages of simvastatin, other domestic and foreign manufacturers of generic simvastatin charged the same or lower prices for simvastatin, including Sandoz, Aurobindo Pharm, Ranbaxy Pharmaceutical, UDL, AHP and Zydus Pharmaceutical.

73. No other foreign or domestic manufacturer of generic simvastatin paid Omnicare an incentive rebate/kickback for its drug.

Substandard Simvastatin from Dr. Reddy's

74. In addition to the higher costs of Dr. Reddy's simvastatin, the quality of the drug has been compromised at least twice, requiring the drug to be recalled. In 2011, 60,000 bottles of 10mg and 40mg simvastatin manufacturer by Dr. Reddy's in India were recalled from the United States as a result of complaints from consumers who detected moldy or musty smells in the tablets.

75. The FDA discovered that trace amounts of the pesticide 2,4,6-tribromanisole (TBA) and other contaminants were present in the recalled batches.

76. TBA is a pesticide that is used to treat the wooden pallets on which pills were stored and transported. TBA has been responsible for several recalls in the pharmaceutical industry in recent years. In some cases, consumers that have ingested pills contaminated with TBA have reported suffering from gastrointestinal illness.

77. The following batches of Dr. Reddy's simvastatin tablets manufactured in Quthbullapur, India have been recalled:

(1) Simvastatin Tablets, USP, 80 mg, 30-count bottles, Rx Only, NDC 55111-268-30. Recall # D-767-2011, CODE Lot #: C002496, Exp. 3/12;

(2) Simvastatin Tablets, USP, 10 mg, 500-count bottles, Rx only, NDC 55111-198-05. Recall # D-768-2011; Lot #: C008115 Exp. 11/12; and

(3) Simvastatin Tablets, USP, 40 mg, 90-count bottles, NDC 55111-200-90, b) 500-count bottles, NDC 55111-200-05, Rx only, Recall # D-769-201,1 Lot #: a) C008195; C008196; C008198; C008200, Exp. 11/13 b) C008197; C008199, Exp. 11/13 59,523 bottles.

VI. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
False Claims Act: Presentation of False Claims
(31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A) as amended in 2009)

78. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

79. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have "knowingly present[ed], or cause[d] to be presented false or fraudulent claim for payment or approval" in violation of 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A) as amended in 2009; and for which Defendants are liable for treble damages plus a civil penalty of $5,500 - $11,000 for each such claim, pursuant to 31 U.S.C. § 3729(a).

80. In particular, Defendants have knowingly caused health care providers to present claims to the United States Government and to Medicaid that were the product of the payment of the above-described kickbacks. The payment of kickbacks to induce prescriptions constitutes a "thing of value . . . for the purpose of improperly obtaining or rewarding favorable treatment," which was designed to and in fact did increase the level of business in violation of the AKA.

81. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

82. By engaging in the conduct described in the foregoing Paragraphs, Defendants have violated the False Claims Act.

SECOND CAUSE OF ACTION
False Claims Act: Making or Using False
Record or Statement to Cause Claim to be Paid
(31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B) as amended in 2009)

83. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

84. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement [*i.e.*, the false certifications and representations made or caused to be made by the Defendants] to get a false or fraudulent claim paid or approved by the Government" in violation of 31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B) as amended in 2009; and for which Defendants are liable for treble damages plus a civil penalty of $5,500 - $11,000 for each such claim, pursuant to 31 U.S.C. § 3729(a).

85. In particular, Defendants have knowingly caused health care providers, to present claims to the United States Government and to Medicaid that were the product of the payment of the above-described kickbacks. The payment of kickbacks to induce prescriptions constitutes a "thing of value . . . for the purpose of improperly obtaining or rewarding favorable treatment," which was designed to and in fact did increase the level of business in violation of the AKA.

86. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

87. By engaging in the conduct described in the foregoing Paragraphs, Defendants have violated the False Claims Act.

THIRD CAUSE OF ACTION
False Claims Act: Making or Using False Record or Statement to Avoid an Obligation to Refund
(31 U.S.C. § 3729(a)(7) and 31 U.S.C. § 3729(a)(1)(G) as amended in 2009)

88. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

89. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants knowingly made, used or caused to be made or used false records or false statements — *i.e.*, the false certifications made or caused to be made by the Defendants — to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States; and for which Defendants are liable for treble damages plus a civil penalty of $5,500 to $11,000 for each such claim, pursuant to 31 U.S.C. § 3729(a) and 31 U.S.C. § 3729(a)(1)(G), as amended in 2009.

90. As a result, Defendants have failed to remit rebates to the Government to which it is entitled.

FOURTH CAUSE OF ACTION
California False Claims Act
(Cal. Govt. Code §§ 12650 *et seq.*)

91. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

92. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Govt. Code §§ 12650 *et seq*.

93. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the State of California or of any political subdivision thereof false or fraudulent claims for the improper payment or

approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

94. The State of California, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

95. By reason of these payments, the State of California has been damaged, and continues to be damaged in a substantial amount.

FIFTH CAUSE OF ACTION
Delaware False Claims and Reporting Act
(6 Del. Code §§ 1201 *et seq.*)

96. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

97. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, 6 Del C. §§ 1201 *et seq*.

98. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the State of Delaware false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin, and used false or fraudulent records to accomplish this purpose.

99. The State of Delaware, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

100. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged in a substantial amount.

SIXTH CAUSE OF ACTION
Florida False Claims Act
(Fla. Stat. §§ 68.081 *et seq.*)

101. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

102. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*

103. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of a Florida state agency false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

104. The State of Florida, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

105. By reason of these payments, the State of Florida has been damaged, and continues to be damaged in a substantial amount.

SEVENTH CAUSE OF ACTION
Georgia False Medicaid Claims Act
(O.C.G.A. §§ 49-4-168 *et seq.*)

106. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

107. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*

108. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Georgia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

109. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

110. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

EIGHTH CAUSE OF ACTION
Hawaii False Claims Act
(Haw. Rev. Stat. §§ 661-21 *et seq.*)

111. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

112. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*

113. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the State of Hawaii false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

114. The State of Hawaii, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

115. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged in a substantial amount.

NINTH CAUSE OF ACTION
Illinois Whistleblower Reward and Protection Act
(740 III. Comp. Stat. §§ 175/1 *et seq.*)

116. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

117. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 III. Comp. Stat. §§ 175/1 *et seq.*

118. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the State of Illinois false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

119. The State of Illinois, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

120. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged in a substantial amount.

TENTH CAUSE OF ACTION
Indiana False Claims and Whistleblower Protection Act
(In. Code §§ 5-11-5.5 *et seq.*)

121. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

122. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, In. Code §§ 5-11-5.5 *et seq.*

123. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Indiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

124. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

125. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

ELEVENTH CAUSE OF ACTION
Louisiana False Claims Act
(46 La. Rev. Stat. Ch. 3 §§ 437.1 *et seq.*)

126. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

127. This is a claim for treble damages and civil penalties under the Louisiana False Claims Act, 46 La. Rev. Stat. Ch. 3 §§ 437.1 *et seq.*

128. By virtue of the acts described above, Defendants offered or paid remuneration, including but not limited to kickbacks, directly or indirectly, overtly or covertly, in cash or in kind, for a good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

129. By virtue of the acts described above, Defendants knowingly presented or caused to be presented a false or fraudulent claim to the State of Louisiana.

130. By virtue of the acts described above, Defendants knowingly engaged in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.

131. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged in a substantial amount.

TWELFTH CAUSE OF ACTION
Massachusetts False Claims Act
(Mass. Gen. Laws ch. 12 §§ 5A *et seq.*)

132. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

133. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 §§ 5A *et seq*.

134. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

135. The State of Massachusetts, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

136. By reason of these payments, the State of Massachusetts has been damaged, and continues to be damaged in a substantial amount.

THIRTEENTH CAUSE OF ACTION
Michigan Medicaid False Claim Act
(M.C.L.S. §§ 400.601 *et seq.*)

137. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

138. This is a claim for civil penalties under the Michigan Medicaid False Claims Act, MCLS §§ 400.601 *et seq.*

139. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be made to the Michigan Medicaid Program false statements or false representations of material fact in the application for Medicaid benefits and for use in determining rights to Medicaid benefits.

140. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

141. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

FOURTEENTH CAUSE OF ACTION
Montana False Claims Act
(Mont. Code. §§ 17-8-401 *et seq.*)

142. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

143. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code §§ 17-8-401 *et seq*.

144. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Montana Medicaid Program false or

fraudulent claims for the improper payment or approval of prescriptions for simvastatin, and used false or fraudulent records to accomplish this purpose.

145. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

146. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

FIFTEENTH CAUSE OF ACTION
Nevada False Claims Act
(Nev. Rev. Stat. §§ 357.010 *et seq.*)

147. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

148. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*

149. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the State of Nevada false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

150. The State of Nevada, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

151. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged in a substantial amount.

SIXTEENTH CAUSE OF ACTION
New Hampshire Medicaid Fraud and False Claims Law
(N.H. Rev. Stat. Ann. §§ 167:61 *et seq.*)

152. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

153. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61, *et seq*.

154. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

155. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

156. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in excess of $5,000.

SEVENTEENTH CAUSE OF ACTION
New Jersey False Claims Act
(N. J. Stat. Ann. §§ 2A:32C-1 *et seq.*)

157. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

158. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N. J. Stat. Ann. §§ 2A:32C-1 *et seq*.

159. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an employee, officer or agent of the state of New Jersey, or to any other contractor, grantee or other recipient of New Jersey funds, false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

160. The State of New Jersey, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

161. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged in a substantial amount.

EIGHTEENTH CAUSE OF ACTION
New Mexico False Claims Act
(N.M.S.A. §§ 27-14-1 *et seq.*)

162. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

163. This is a claim for treble damages and civil penalties under the New Mexico False Claims Act, N.M.S.A. §§ 27-14-1 *et seq.*

164. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

165. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

166. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

NINETEENTH CAUSE OF ACTION
New York False Claims Act
(N.Y. Fin. Law §§ 187 *et seq.*)

167. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

168. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 *et seq.*

169. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an employee, officer or agent of the state of

New York or a local government therein false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

170. The State of New York, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

171. By reason of these payments, the State of New York has been damaged, and continues to be damaged in a substantial amount.

TWENTIETH CAUSE OF ACTION
North Carolina False Claims Act
(N. C. Gen. Stat. Ann. §§ 1-605 *et seq.*)

172. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

173. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N. C. Gen. Stat. Ann. §§ 1-605 *et seq*.

174. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the State of North Carolina false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

175. The State of North Carolina, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

176. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged in a substantial amount.

TWENTY-FIRST CAUSE OF ACTION
Oklahoma Medicaid False Claims Act
(Okla. Stat. Ann. §§ 5053 *et seq.*)

177. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

178. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. §§ 5053 *et seq.*

179. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the State of Oklahoma false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

180. The State of Oklahoma, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

181. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-SECOND CAUSE OF ACTION
Rhode Island False Claims Act
(R. I. St. §§ 9-1.1-1 *et seq.*)

182. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

183. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act, R. I. St. §§ 9-1.1-1 *et seq.*

184. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the state of Rhode Island fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

185. The State of Rhode Island, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

186. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged in a substantial amount.

TWENTY-THIRD CAUSE OF ACTION
Tennessee Medicaid False Claims Act
(Tenn. Code §§ 71-5-181 *et seq.*)

187. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

188. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code §§ 71-5-181 *et seq.*

189. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the State of Tennessee false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

190. The State of Tennessee, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

191. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged in a substantial amount.

TWENTY-FOURTH CAUSE OF ACTION
Texas Medicaid Fraud Prevention Law
(Tex. Hum. Res. Code §§ 36.001 *et seq.*)

192. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

193. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001 *et seq.*

194. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly made or caused to be made to the Texas Medicaid Program false statements or misrepresentations of material fact, and knowingly concealed or failed to disclose information to permit persons to receive benefits or payments under the Texas Medicaid Program for simvastatin that were not authorized or that were greater than the benefit or payment that was authorized, and used false or fraudulent records to accomplish this purpose.

195. Defendants knowingly paid, charged, solicited accepted or received, in addition to an amount paid under the Texas Medicaid Program, a gift, money, a donation or other consideration as a condition to the provision of a service or product or the continued provision of a service or product where cost of the service or product was paid for, in whole or in part, under the Texas Medicaid Program.

196. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

197. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-FIFTH CAUSE OF ACTION
Virginia Fraud against Taxpayers Act
(Va. Code §§ 8.01-216.1 *et seq.*)

198. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

199. This is a claim for treble damages and civil penalties under the Virginia Fraud against Taxpayers Act, Va. Code §§ 8.01-216.1 *et seq.*

200. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the Commonwealth of

Virginia false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

201. The Virginia Commonwealth, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

202. By reason of these payments, the Virginia Commonwealth has been damaged, and continues to be damaged in a substantial amount.

TWENTY-SIXTH CAUSE OF ACTION
Wisconsin False Claims Act
(Wis. Stat. Ann. §§ 20.931 (1) *et seq.*)

203. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

204. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act, Wis. Stat. Ann. §§ 20.931 (1) *et seq*.

205. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer, employee or agent of the State of Wisconsin false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

206. The State of Wisconsin, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

207. By reason of these payments, the State of Wisconsin has been damaged, and continues to be damaged in a substantial amount.

TWENTY-SEVENTH CAUSE OF ACTION
District of Columbia False Claims Act
(D.C. Code §§ 2-308.13 *et seq.*)

208. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

209. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code §§ 2-308.13 *et seq*.

210. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the District of Columbia false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

211. The District of Columbia, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

212. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged in a substantial amount.

TWENTY-EIGHTH CAUSE OF ACTION
Chicago False Claims Act
(Mun. Code Ch. 1 §§ 22-010 *et seq*.)

213. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

214. This is a claim for treble damages and civil penalties under the Chicago False Claims Act, Mun. Code Ch. 1 §§ 22-010 *et seq*.

215. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer, employee or agent of the City of Chicago false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

216. The City of Chicago, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

217. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged in a substantial amount.

TWENTY-NINTH CAUSE OF ACTION
New York City False Claims Act
(N.Y.C. Admin. Code §§ 7-801 *et seq.*)

218. Relator re-alleges and incorporates by reference herein the allegations previously alleged.

219. This is a claim for treble damages and civil penalties under the New York City False Claims Act, N.Y.C. Admin. Code §§ 7-801 *et seq*.

220. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer, employee or agent of the City of New York false or fraudulent claims for the improper payment or approval of prescriptions for simvastatin and used false or fraudulent records to accomplish this purpose.

221. The City of New York, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

222. By reason of these payments, the City of New York has been damaged, and continues to be damaged in a substantial amount.

VII. PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States Government, the States and Cities, demands judgment against the above-named Defendants, ordering that:

As to the Federal Claims:

a. Pursuant to 31 U.S.C. § 3729(a), Defendants pay: an amount equal to three times the amount of damages the United States Government has sustained as a result of Defendants' actions, which Relator currently estimates to be in the hundreds of millions of dollars; plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §§ 3729 *et seq.*, or such other penalty as the law may permit and/or require for each violation of other laws which governed Defendants' conduct.

b. Relator be awarded a realtor's share of the judgment to the maximum amount provided pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(o) and any other applicable provision of the law; and

As to the State Claims:

d. As provided by the following state and city laws, Relator and each named State Plaintiff be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each state and city as a result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendants within each state and city; Relator be awarded relator's share of any judgment; Relator be awarded all costs and expenses associated with each of the pendent state and city claims, plus attorneys' fees:

Cal. Govt. Code §§12650 *et seq.*;
6 Del. C. §§ 1201 *et seq.*;
Fla. Stat. Ann. §§ 68.081 *et seq.*;
O.C.G.A. §§ 49-4-168 *et seq.*;
Haw. Rev. Stat. §§ 661-21 *et seq.*;
740 Ill. Comp. Stat. §§ 175/1 *et seq.*;
In. Code §§ 5-11-5.5 *et seq.*;
46 La. Rev. Stat. ch. 3, §§ 437.1 *et seq.*;
Mass. Gen. Laws Ch. 12 §§ 5A *et seq.*;
MCLS §§ 400.601 *et seq.*
Mont. Code §§ 17-8-401 *et seq.*;
Nev. Rev. Stat. Ann. §§ 357.010 *et seq.*;
N.H. Rev. Stat. Ann. §§ 167:61 *et seq.*;
N. J. Stat. Ann. §§ 2A:32C-1 *et seq.*;
N.M.S.A. §§ 27-14-1 *et seq.*;
N.Y. Fin. Law §§ 187 *et seq.*;
N. C. Gen. Stat. Ann. §§1-605 *et seq.*;
Okla. Stat. Ann. §§ 5053 *et seq.*;
R. I. St. §§ 9-1.1-1 *et seq.*;
Tenn. Code Ann. §§ 71-5-181 *et seq.*;
Tex. Hum. Res. Code §§ 36.001 *et seq.*;
Va. Code. Ann. § 8.01-216.1 *et seq.*;
Wis. Stat. Ann. §§20.931 (1) *et seq.*;

D.C. Code Ann. §§ 2-308.13 *et seq.*;
Chicago False Claims Act, Mun. Code ch.1, §§ 22-010 *et seq.; and*
New York City False Claims Act, N.Y.C. Admin. Code §§ 7-801 *et seq.*

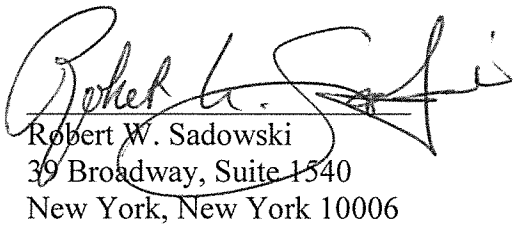
e. Relator, the United States and the State and City Plaintiffs be awarded such other and further relief as the Court may deem to be just and proper.

f. JURY DEMAND

Relator hereby demands a trial by jury as to all issues.

Dated: New York, New York
June 3, 2013

SADOWSKI FISCHER PLLC



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